

Lot No.: **72E**

Lot-specific information

Olerup SSP[®] DRB1*08

Product number: 101.127-12u/04u – without *Taq* pol.
Lot number: 72E
Expiry date: 2010-June-01
Number of tests: 12 tests – Product No. 101.127-12u
4 tests – Product No. 101.127-04u
Number of wells per test: 24
Storage - pre-aliquoted primers: dark at -20°C
- PCR Master Mix: -20°C
- Adhesive PCR seals RT
- Product Insert RT

This Product Description is only valid for Lot No. 72E.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] DRB1*08 LOT

The DRB1*08 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP*[®] DRB1*08 lot was made (**Lot No. X72**).

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
13	-	Added	Primer added for the DRB1*0833 allele.
22	-	Added	Primer added for the DRB1*0834 allele.

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PRODUCT DESCRIPTION

DRB1*08 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*0801 to DRB1*0834 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well cut PCR plate is marked with 'DRB1*08'.

Well No. 1 is marked with the Lot No. '72E'.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of DRB1*08 SSP subtypings will be influenced by one DRB1*03 allele, seven DRB1*04 alleles, seven DRB1*11 alleles, all DRB1*12 alleles, several DRB1*13 alleles, several DRB1*14 alleles and two DRB1*15 allele when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*08 alleles, i.e. **DRB1*0801 to DRB1*0834**, recognized by the HLA Nomenclature Committee in April 2008¹ will give rise to unique amplification patterns by the primers in the DRB1*08 subtyping kit².

The DRB1*08 subtyping kit cannot distinguish the DRB1*080101 to DRB1*080103 alleles, the DRB1*080201 to DRB1*080203 alleles, the DRB1*080401 and DRB1*080404 alleles or the DRB1*080402 and DRB1*080403 alleles.

¹DRB1 alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, www.ebi.ac.uk/imgt/hla.

²The DRB1*0820 and DRB1*1412 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These two alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 34 DRB1*08 alleles can be combined in 595 homozygous and heterozygous combinations. 205 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific products in vials 12, 13, 17, 18, 19, 22 and 24 were not considered in these calculations.

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++++++- - - - - + - - - - -	0802,0818 = 0803,0824
+++++--+ ++- - - - + + - - - -	0809,0812 = 0812,0821
+++++--+ + - - - - + + - - - -	0809,0810 = 0810,0821
+++++--+ - - - - + - + - - - + -	0803,0828 = 0828,0829
+++++--+ - - - - - + + - - - -	0803,0804 = 0804,0829
+++++--+ + - - - - + - - - - -	0809,0827 = 0821,0827
+++++--+ + - - - - + - - - - -	0809,0833 = 0821,0833
+++++--+ + - - - - + - + - - - -	0809,0832 = 0821,0832
+++++--+ + - - - - + - - - - + -	0809,0823 = 0821,0823
+++++--+ + - - - - + - - - - -	0803,0809 = 0803,0821 = 0809,0829
+++++--+ - - - - - + - - - - -	0802,0803 = 0802,0829
++++-++- - - - - - + - - - - -	0818,0824 = 0824,0829
+++-+++- - - - - - - - - - - -	0801,0824 = 0802,0805
+++-+++- ++- - - - - + - - - - -	0809,0822 = 0821,0822
+++-+++- + - - - - - + - - - - -	0806,0809 = 0806,0821
+++-+++- - - - - + - + - - - + -	0801,0828 = 0804,0817 = 0817,0828
+++-+++- + - - - - + - - - - -	0809,0817 = 0817,0821
+++-+++- + - - - - - - + - - - -	0809,0816 = 0816,0821
+++-+++- + - - - - - - - - - +	0809,0826 = 0821,0826
+++-+++- + - - - - - - - - - -	0801,0809 = 0801,0821
++-++-+- - - - + - - + - - - - -	0803,0813 = 0813,0827 = 0813,0829 = 0827,0830
++-++-+- - - - - - + - - - - -	0803,0830 = 0829,0830
+ - - + + + + + - + - - - - + + - - - -	0805,0812 = 0818,0822
+ - - + + + + + - - - - - + + - - - -	0805,0810 = 0806,0818
+ - - + + + + + - - - - + - + - - - -	0805,0833 = 0811,0818
+ - - + + + + + - - - - - + - - - - -	0801,0825 = 0805,0834
+ - - + + + + + - - - - - + - + - - - -	0807,0818 = 0816,0818
+ - - + + + + + - - - - - + - - - - -	0801,0818 = 0803,0805
+ - - + + + + + - + - - + - + + - - - -	0811,0812 = 0822,0833
+ - - + + + + + - + - - - - + + + - - - -	0807,0812 = 0812,0816
+ - - + + + + + - + - - - - + + - - - +	0812,0826 = 0814,0822
+ - - + + + + + - + - - - - + + - - - -	0801,0812 = 0803,0822 = 0822,0829
+ - - + + + + + - - - - + - + + - - - -	0806,0833 = 0810,0811
+ - - + + + + + - - - - - + + + - - - -	0807,0810 = 0810,0816
+ - - + + + + + - - - - - + + - - - + +	0806,0814 = 0810,0826
+ - - + + + + + - - - - - + + - - - -	0801,0810 = 0803,0806 = 0806,0829
+ - - + + + + + - - + - - - + - - - - -	0803,0808 = 0808,0829
+ - - + + + + + - - - - + - + - - - -	0807,0827 = 0816,0827
+ - - + + + + + - - - - + - + - - - -	0807,0833 = 0816,0833
+ - - + + + + + - - - - + - + - - - -	0801,0833 = 0803,0811 = 0811,0829 = 0811,0833
+ - - + + + + + - - - - + - + - - - -	0803,0817 = 0817,0829
+ - - + + + + + - - - - - + + + - - - +	0807,0814 = 0814,0816
+ - - + + + + + - - - - - + + - - - +	0801,0814 = 0814,0826
+ - - + + + + + - - - - - + - + - - - -	0807,0832 = 0816,0832
+ - - + + + + + - - - - - + - + - - - -	0807,0823 = 0816,0823
+ - - + + + + + - - - - - + - + - - - -	0803,0807 = 0803,0816 = 0807,0829 = 0816,0829
+ - - + + + + + - - - - - + - - - - +	0803,0826 = 0826,0829
+ - - + + + + + - - - - - + - - - - -	0801,0803 = 0801,0829
+ - - + + + + + - + - - - - + + - - - -	0806,0812 = 0810,0822
+ - - + + + + + - - + - - - + - - - - +	0818,0831 = 0829,0831



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+--+---+ - - - - - + - - - - - 0805,0818 = 0805,0829
+--+---+ - - - - - - - + - - - - 0805,0807 = 0805,0816
+--+---+ - + - - - - - +--+---+ 0807,0822 = 0816,0822
+--+---+ - - - - - - - +--+---+ 0806,0807 = 0806,0816
+--+---+ - - - - - + - - - + - - - 0807,0817 = 0816,0817
+--+---+ - - - - - + - - - + - - - 0801,0817 = 0817,0817
+--+---+ - - - - - - - + - - - + 0807,0826 = 0816,0826
+--+---+ - - - - - - - + - - - - 0801,0807 = 0801,0816 = 0807,0816 =
0816,0816
+--+---+ - - - - - - - - - - + 0801,0826 = 0826,0826
+---++++ - - - - - + - - - - + - - 0818,0819 = 0823,0825
+---++++ - - - - - + - - - - - 0803,0825 = 0818,0834
+---++++ - + - - - - - + - - - - - 0803,0812 = 0812,0829
+---++++ - - - - - + - - - + - - - 0803,0810 = 0810,0829
+---++++ - - + - - - - + - - - - - 0803,0815 = 0815,0829
+---++++ - - - + - - - + - - - - - 0803,0827 = 0827,0827 = 0827,0829
+---++++ - - - - - + - - - - - 0803,0833 = 0829,0833 = 0833,0833
+---++++ - - - - - + - - - - + - - 0803,0819 = 0819,0823 = 0819,0829 =
0823,0834
+---++++ - - - - - + - - - - - 0803,0834 = 0829,0834
+---++++ - - - - - + + - - - - + 0814,0820 = 0814,0832
+---++++ - - - - - + + - - - - - 0803,0820 = 0820,0829 = 0820,0832
+---++++ - - - - - + - + - - - - - 0803,0832 = 0829,0832 = 0832,0832
+---++++ - - - - - + - - - - + - - 0803,0823 = 0823,0823 = 0823,0829
+---++++ - - - - - + - - - - - 0803,0803 = 0803,0829
+---++++ - - - - - + - - - - - 0818,0825 = 0825,0829
+---++++ - - - - - + - - - - - 0818,0818 = 0818,0829
+---++++ - - - - - + - - - - + 0814,0814 = 0814,0829
-+++++ - - - - - + - - - - - 0802,0825 = 0824,0834
-+++++ - + - + - - - - - - - - - - 0809,0815 = 0815,0821
-+++++ - + - - - - - + - - - - + - - 0809,0819 = 0819,0821
-+++++ - + - - - - - + - - - - - 0809,0834 = 0821,0834
-+++++ - + - - - - - - - - - - 0809,0830 = 0821,0830
-+++++ - - + - - - - - - - - - - 0802,0815 = 0808,0830
-+++---+ + - - - - - + - - - + - - - 0809,0828 = 0821,0828
-+++---+ + - - - - - + - - - + - - - 0804,0809 = 0804,0821
-+++---+ + - + - - - - - - - - - - 0808,0809 = 0808,0821
-+++---+ + - - - - - - - - - - 0809,0813 = 0813,0821
-+++---+ + - - - - - - - - - - 0809,0811 = 0811,0821
-+++---+ + - - - - - + - - - - - 0809,0820 = 0820,0821
-+++---+ + - - - - - - - + - - - - 0807,0809 = 0807,0821
-+++---+ + - - - - - - - - - - 0802,0809 = 0802,0821 = 0809,0809 =
0809,0821
-+++---+ - - - - - + - - - + - - - 0804,0828 = 0828,0828
-+++---+ - - - - - + - - - + - - - 0819,0819 = 0819,0834

0801 = 080101-080103
0802 = 080201-080203
0803 = 080302
0804 = 080401-080404
0820 = 0820 + 1412



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SPECIFICITY TABLE

DRB1*08 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB1*08 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*08 alleles ³	Other amplified DRB1 alleles ⁴
1	165 bp	515 bp	080101-080103, 080302, 0805, 0806, 0810, 0812, 0814, 0816-0818, 0822, 0823, 0826, 0827, 0829, 0832, 0833	
2	165 bp	430 bp	080201-080203, 080401-080404, 0809, 0813, 0821, 0824, 0828, 0830	1209, 1317, 1415, 1452
3	195 bp	430 bp	080101-080203, 080401-0809, 0811, 0816, 0817, 0821, 0822, 0824, 0826, 0828, 0831	1167, 120201-120202, 1213, 1215, 1216, 1415, 1473
4	195 bp	430 bp	080302, 0810, 0812, 0814, 0815, 0818, 0819, 0823, 0825, 0827, 0829, 0830, 0832-0834	120101-120102, 120302-1206, 1208-1211, 1214, 1317
5 ⁵	225 bp	515 bp	080101-080203, 080302-080404, 0806-0813, 0815-0817, 0819, 0820, 0822, 0823, 0826-0828, 0830, 0832-0834	1123, 1125, 1145, 1155, 1164, 1167, 1313, 1318, 1347, 1355, 140301-140302, 1412, 1415, 1427, 1440, 1455, 1463, 1467, 1477
6	215 bp	430 bp	0805, 0818, 0824, 0825, 0831	120101-120202, 120302-1216, 1317, 1431, 1452
7	250 bp	430 bp	080101-080203, 080302, 0805, 0807-0809, 0811, 0813-0819, 0821, 0823-0827, 0829, 0830, 0832-0834	1216, 1468
8	250 bp	430 bp	080401-080404, 0806, 0810, 0812, 0822, 0828, 0831	1167, 120101-120202, 120302-1215, 1317, 1404, 1411, 1415, 1428, 1431, 1450, 1452, 1471, 1473, 1476

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9	150 bp	430 bp	0809, 0821	1415, 1440, 1455, 1477
10⁶	250 bp	430 bp	0812, 0822	120101-120202, 1204-1215, 1428
11⁶	170 bp	430 bp	0808, 0815, 0831	1167, 1204, 1404, 1411, 1428, 1431, 1450, 1468, 1471, 1473, 1476
12⁷	95, 195 bp	515 bp	0813, 0827	1212
13⁸	135, 165 bp	430 bp	0811, 0833	
14	135 bp	430 bp	0817, 0828	1167, 120101-120202, 120302-1216, 1317
15	165 bp	430 bp	0819, 0825, 0834	120101-120202, 120302, 1205-1208, 1210-1216
16	70 bp	430 bp	080302, 0810, 0812, 0814, 0818, 0823, 0827, 0829, 0832, 0833	0412, 130301-1304, 1312, 1313, 1330, 1332, 1333, 1338, 1348, 1358, 1365, 1366, 1381, 1463
17⁹	75, 175 bp	430 bp	080401, 080402-080403 ^{weakly} , 080404, 0806, 0810, 0812, 0814, 0820, 0822, 0828	0412, 0418, 0425, 0458, 1125, 1167, 1318, 1412, 1415, 1521
18¹⁰	150, 225 bp	430 bp	0820, 0832	1123, 1125, 1145, 1155, 1164, 1313, 1318, 1347, 1355, 140301-140302, 1412, 1427, 1440, 1455, 1463, 1467, 1477
19¹¹	105, 165 bp	515 bp	0807, 0816	
20	125 bp	515 bp	0806, 0810, 0812, 0822	0312, 0410-0412, 0467, 1304, 1332, 1348, 1358, 1375, 1381, 1465, 1512
21	120 bp	515 bp	0817, 0828	1123, 1125, 1145, 1155, 1164, 1167, 1318, 1521
22¹²	130, 165 bp	430 bp	0819, 0823	
23	250 bp	430 bp	080401, 080402-080403 ^{weakly} , 080404, 0806, 0810, 0828, 0831	1167, 120302, 1317, 1404, 1411, 1415, 1431, 1450, 1452, 1473, 1476
24¹³	135, 175 bp	430 bp	0814, 0826	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB1*08SSP subtyping. When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter

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than 20 base pairs are not given. For high resolution SSP kits the respective length of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB1*08 subtyping.

In addition, wells number 5, 12, 19, 20 and 21 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³For several DRB alleles only partial second exon and fourth exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the first hyperpolymorphic region of the second exon of DRB alleles are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*0101 consensus sequence.

⁴Due to the sharing of sequence motifs within the DR52 group of DRB1 alleles, one DRB1*03 alleles, seven DRB1*04 alleles, seven DRB1*11 alleles, all DRB1*12 alleles, several DRB1*13 alleles and several DRB1*14 alleles and two DRB1*15 allele are amplified by some of the DRB1*08 primer mixes.

The DRB1*0820 and DRB1*1412 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These two alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

⁵Primer mix 5 has a tendency of giving rise to nonspecific amplifications.

⁶Primer mixes 10 and 11 have a tendency of giving rise to a primer oligomer artifact.

⁷Primer mix 12: Specific PCR fragment of 95 bp in the DRB1*0827 allele. Specific PCR fragment of 195 bp in the DRB1*0813 and DRB1*1212 alleles.

⁸Primer mix 13: Specific PCR fragment of 135 bp in the DRB1*0833 allele. Specific PCR fragment of 165 bp in the DRB1*0811 allele.

⁹Primer mix 17: Specific PCR fragment of 75 bp in the DRB1*080401-080404, 0806, 0810, 0812, 0820, 0822, 0828 and DRB1*0412, 0418, 0425, 0458, 1125, 1167, 1318, 1412, 1415 and 1521 alleles. Specific PCR fragment of 175 bp in the DRB1*0814 allele.

¹⁰Primer mix 18: Specific PCR fragment of 150 bp in the DRB1*0832 allele. Specific PCR fragment of 225 bp in the DRB1*0820 and DRB1*1123, 1125, 1145, 1155, 1164, 1313, 1318, 1347, 1355, 140301-140302, 1412, 1427, 1440, 1455, 1463, 1467 and 1477 alleles.

¹¹Primer mix 19: Specific PCR fragment of 105 bp in the DRB1*0816 allele. Specific PCR fragment of 165 bp in the DRB1*0807 allele.

¹²Primer mix 22: Specific PCR fragment of 130 bp in the DRB1*0819 allele. Specific PCR fragment of 165 bp in the DRB1*0823 allele.

¹³Primer mix 24: Specific PCR fragment of 135 bp in the DRB1*0826 allele. Specific PCR fragment of 175 bp in the DRB1*0814 allele.

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INTERPRETATION TABLE												
DRB1*08 SSP subtyping												
Amplification patterns of the DRB1*0801 to 0834 alleles												
	Well⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	165	165	195	195	225	215	250	250	150	250	170	95
PCR product												195
Length of int.	515	430	430	430	515	430	430	430	430	430	430	515
pos. control ¹												
5'-primer(s) ²	16	16	16	16	12	16	16	16	37	16	16	16
	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-T AC ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-g TT ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}
3'-primer(s) ³	57	57	67	67	74	74	86	86	74	85	58	34
	5'-gCT ^{3'}	5'-C AT ^{3'}	5'-gAA ^{3'}	5'-gAT ^{3'}	5'-CAG ^{3'}	5'-CgC ^{3'}	5'-C AC ^{3'}	5'-C CA ^{3'}	5'-CAg ^{3'}	5'-C Ag ^{3'}	5'-TC C ^{3'}	5'-C TC ^{3'}
								86			58	67
								5'-C AA ^{3'}			5'-TC C ^{3'}	5'-gAg ^{3'}
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele ⁴												
*080101-080103	1		3		5		7					
*080201-080203		2	3		5		7					
*080302	1			4	5		7					
*080401, 080404		2	3		5			8				
*080402-080403		2	3		5			8				
*0805	1		3			6	7					
*0806	1		3		5			8				
*0807			3		5		7					
*0808			3		5		7				11	
*0809		2	3		5		7		9			
*0810	1			4	5			8				
*0811			3		5		7					
*0812	1			4	5			8		10		
*0813		2			5		7					12
*0814	1			4			7					
*0815				4	5		7				11	
*0816	1		3		5		7					
*0817	1		3		5		7					
*0818	1			4		6	7					
*0819				4	5		7					
*0820, 1412 ⁶					5							
*0821		2	3				7		9			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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DRB1*08 SSP subtyping												
Amplification patterns of the DRB1*0801 to 0834 alleles												
Well ⁵												
13	14	15	16	17	18	19	20	21	22	23	24	
135	135	165	70	75	150	105	125	120	130	250	135	Length of spec.
165				175	225	165			165		175	PCR product
430	430	430	430	430	430	515	515	515	430	430	430	Length of int.
												pos. control ¹
16	16	16	57	12	13	16	57	47	16	16	12	5'-primer(s) ²
5'-gT T ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-AgC ^{3'}	5'-T Ag ^{3'}	5'-g TC ^{3'}	5'-gT T ^{3'}	5'-AgC ^{3'}	5'-g TT ^{3'}	5'-gT T ^{3'}	5'-gT T ^{3'}	5'-T Ag ^{3'}	
				74	37						25	
				5'-C CT ^{3'}	5'-Ag C ^{3'}						5'-g CT ^{3'}	
48	47	57	67	57	74	37	86	74	45	85	57	3'-primer(s) ³
5'-CCA ^{3'}	5'-g gA ^{3'}	5'-C gA ^{3'}	5'-gAT ^{3'}	5'-gCT ^{3'}	5'-CAg ^{3'}	5'-gTC ^{3'}	5'-C CA ^{3'}	5'-CAg ^{3'}	5'-CCT ^{3'}	5'-C AA ^{3'}	5'-gCT ^{3'}	
57				86		57			57			
5'-C Ag ^{3'}				5'-C CA ^{3'}		C AA			5'-C gA ^{3'}			
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												DRB1 allele ⁴
												*080101-080103
												*080201-080203
			16									*080302
				17						23		*080401, 080404
				w						w		*080402-080403
												*0805
				17			20			23		*0806
						19						*0807
												*0808
												*0809
			16	17			20			23		*0810
13												*0811
			16	17			20					*0812
												*0813
			16	17							24	*0814
												*0815
						19						*0816
	14							21				*0817
			16									*0818
		15							22			*0819
				17	18							*0820, 1412 ⁶
												*0821
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **72E**

Lot-specific information

Length of spec.	165	165	195	195	225	215	250	250	150	250	170	95
PCR product												195
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0822	1		3		5			8		10		
*0823	1			4	5		7					
*0824		2	3			6	7					
*0825				4		6	7					
*0826	1		3		5		7					
*0827	1			4	5		7					12
*0828		2	3		5			8				
*0829	1			4			7					
*0830		2		4	5		7					
*0831			3			6		8			11	
*0832	1			4	5		7					
*0833	1			4	5		7					
*0834				4	5		7					
*0312, 0410, 0411, 0467, 1375, 1465, 1512												
*0412												
*0418, 0425, 0458												
*1123, 1145, 1155, 1164					5							
*1125, 1318					5							
*1167			3		5			8			11	
*120101-120102, 1205, 1206, 1208, 1210, 1211, 1214				4		6		8		10		
*120201-120202, 1213, 1215			3			6		8		10		
*120302				4		6		8				
*1204				4		6		8		10	11	
*1207						6		8		10		
*1209		2		4		6		8		10		
*1212						6		8		10		12
*1216			3			6	7					
*130301-130302, 1312, 1330, 1333, 1338, 1365, 1366												
*1304, 1332, 1348, 1358, 1381												
*1313, 1463					5							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **72E**

Lot-specific information

135	135	165	70	75	150	105	125	120	130	250	135	Length of spec. PCR product Well No.
165				175	225	165			165		175	
13	14	15	16	17	18	19	20	21	22	23	24	
				17			20					*0822
			16						22			*0823
												*0824
		15										*0825
											24	*0826
			16									*0827
	14			17				21		23		*0828
			16									*0829
												*0830
										23		*0831
			16		18							*0832
13			16									*0833
		15										*0834
							20					*0312, 0410, 0411, 0467, 1375, 1465, 1512
			16	17			20					*0412
				17								*0418, 0425, 0458
					18			21				*1123, 1145, 1155, 1164
				17	18			21				*1125, 1318
	14			17				21		23		*1167
	14	15										*120101-120102, 1205, 1206, 1208, 1210, 1211, 1214
	14	15										*120201-120202, 1213, 1215
	14	15								23		*120302
	14											*1204
	14	15										*1207
	14											*1209
	14	15										*1212
	14	15										*1216
			16									*130301-130302, 1312, 1330, 1333, 1338, 1365, 1366
			16				20					*1304, 1332, 1348, 1358, 1381
			16		18							*1313, 1463
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **72E**

Lot-specific information

Length of spec.	165	165	195	195	225	215	250	250	150	250	170	95
PCR product												195
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1317		2		4		6		8				
*1347, 1355, 140301-140302, 1427, 1467					5							
*1404, 1411, 1450, 1476								8			11	
*1415		2	3		5			8	9			
*1428								8		10	11	
*1431						6		8			11	
*1440, 1455, 1477					5				9			
*1452		2				6		8				
*1468							7				11	
*1471								8			11	
*1473			3					8			11	
*1521												
DRB1 allele ⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB1*08 subtyping.

In addition, wells number 5, 12, 19, 20 and 21 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The codon, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

³The codon, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

Lot No.: **72E**

Lot-specific information

135	135	165	70	75	150	105	125	120	130	250	135	Length of spec. PCR product
165				175	225	165			165		175	Well No.
13	14	15	16	17	18	19	20	21	22	23	24	
	14									23		*1317
				18								*1347, 1355, 140301-140302, 1427, 1467
										23		*1404, 1411, 1450, 1476
				17						23		*1415
										23		*1428
												*1431
					18							*1440, 1455, 1477
										23		*1452
												*1468
										23		*1471
				17				21				*1473
												*1521
												DRB1 allele ⁴
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

⁴The sequence of the DRB1*080301 allele has been shown to be identical to DRB1*080302.

⁵Primer mix 12: Specific PCR fragment of 95 bp in the DRB1*0827 allele. Specific PCR fragment of 195 bp in the DRB1*0813 and DRB1*1212 alleles.

Primer mix 13: Specific PCR fragment of 135 bp in the DRB1*0833 allele. Specific PCR fragment of 165 bp in the DRB1*0811 allele.

Primer mix 17: Specific PCR fragment of 75 bp in the DRB1*080401-080404, 0806, 0810, 0812, 0820, 0822, 0828 and DRB1*0412, 0418, 0425, 0458, 1125, 1167, 1318, 1412, 1415 and 1521 alleles. Specific PCR fragment of 175 bp in the DRB1*0814 allele.

Primer mix 18: Specific PCR fragment of 150 bp in the DRB1*0832 allele. Specific PCR fragment of 225 bp in the DRB1*0820 and DRB1*1123, 1125, 1145, 1155, 1164, 1313, 1318, 1347, 1355, 140301-140302, 1412, 1427, 1440, 1455, 1463, 1467 and 1477 alleles.

Primer mix 19: Specific PCR fragment of 105 bp in the DRB1*0816 allele. Specific PCR fragment of 165 bp in the DRB1*0807 allele.

Primer mix 22: Specific PCR fragment of 130 bp in the DRB1*0819 allele. Specific PCR fragment of 165 bp in the DRB1*0823 allele.

Primer mix 24: Specific PCR fragment of 135 bp in the DRB1*0826 allele. Specific PCR fragment of 175 bp in the DRB1*0814 allele.

⁶The DRB1*0820 and DRB1*1412 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These two alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

'w', may be weakly amplified.

Lot No.: **72E**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*08 SSP subtyping kit																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	IHWC cell line	DRB1			200321601	200321602	200321603	200417104	200321605	200321606	200321607	200321608	200321609	200321610	200321611	200417112	200847613	200321614	200321615	200417116
1	9001 SA	*0101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*1502	*0405		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*1502			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*1601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0407	*0803		+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
7	9020 QBL	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM	*0401	*1602		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*0402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*0405			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*0701			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0701			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB	*0801			+	-	+	-	+	-	+	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*0802			-	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
15	9075 DKB	*0901			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*1101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*1501			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*0901	*1101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*1201			-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-
20	9059 SLE005	*1302			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*1402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*1302	*1401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0803	*1414		+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
24	9035 JBUSH	*1101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*0701			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*0405	*1001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0416	*0701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*0701			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*0302			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*1303			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
33	9098 MT14B	*0404			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*1101			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*0403			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*0403	*0406		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*1301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*1402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0301	*0401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*0701	*0901		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*1302			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0803			+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
43	9076 T7526	*0901			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*1401			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*0701			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*1501			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*1104	*1201		-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-
48	9303 TER-ND	*0103			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **72E**

Lot-specific information

CELL LINE VALIDATION SHEET												
DRB1*08 SSP subtyping kit												
				Well								
				17	18	19	20	21	22	23	24	
				200621217	200621218	200321619	200321620	200321621	200847622	200321623	200417124	
				Prod. No.:								
IHWC cell line		DRB1										
1	9001	SA	*0101		-	-	-	-	-	-	-	-
2	9280	LK707	*1502	*0405	-	-	-	-	-	-	-	-
3	9011	E4181324	*1502		-	-	-	-	-	-	-	-
4	9275	GU373	*0301		-	-	-	-	-	-	-	-
5	9009	KAS011	*1601		-	-	-	-	-	-	-	-
6	9353	SM	*0407	*0803	-	-	-	-	-	-	-	-
7	9020	QBL	*0301		-	-	-	-	-	-	-	-
8	9007	DEM	*0401	*1602	-	-	-	-	-	-	-	-
9	9026	YAR	*0402		-	-	-	-	-	-	-	-
10	9107	LKT3	*0405		-	-	-	-	-	-	-	-
11	9051	PITOUT	*0701		-	-	-	-	-	-	-	-
12	9052	DBB	*0701		-	-	-	-	-	-	-	-
13	9067	BTB	*0801		-	-	-	-	-	-	-	-
14	9071	OLGA	*0802		-	-	-	-	-	-	-	-
15	9075	DKB	*0901		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*1101		-	-	-	-	-	-	-	-
17	9008	WILJON	*1501		-	-	-	-	-	-	-	-
18	9257	32367	*0901	*1101	-	-	-	-	-	-	-	-
19	9038	BM16	*1201		-	-	-	-	-	-	-	-
20	9059	SLE005	*1302		-	-	-	-	-	-	-	-
21	9064	AMALA	*1402		-	-	-	-	-	-	-	-
22	9056	KOSE	*1302	*1401	-	-	-	-	-	-	-	-
23	9124	IHL	*0803	*1414	-	-	-	-	-	-	-	-
24	9035	JBUSH	*1101		-	-	-	-	-	-	-	-
25	9049	IBW9	*0701		-	-	-	-	-	-	-	-
26	9285	WT49	*0301		-	-	-	-	-	-	-	-
27	9191	CH1007	*0405	*1001	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*0416	*0701	-	-	-	-	-	-	-	-
29	9050	MOU	*0701		-	-	-	-	-	-	-	-
30	9021	RSH	*0302		-	-	-	-	-	-	-	-
31	9019	DUCAF	*0301		-	-	-	-	-	-	-	-
32	9297	HAG	*1303		-	-	-	-	-	-	-	-
33	9098	MT14B	*0404		-	-	-	-	-	-	-	-
34	9104	DHIF	*1101		-	-	-	-	-	-	-	-
35	9302	SSTO	*0403		-	-	-	-	-	-	-	-
36	9024	KT17	*0403	*0406	-	-	-	-	-	-	-	-
37	9065	HHKB	*1301		-	-	-	-	-	-	-	-
38	9099	LZL	*1402		-	-	-	-	-	-	-	-
39	9315	CML	*0301	*0401	-	-	-	-	-	-	-	-
40	9134	WHONP199	*0701	*0901	-	-	-	-	-	-	-	-
41	9055	H0301	*1302		-	-	-	-	-	-	-	-
42	9066	TAB089	*0803		-	-	-	-	-	-	-	-
43	9076	T7526	*0901		-	-	-	-	-	-	-	-
44	9057	TEM	*1401		-	-	-	-	-	-	-	-
45	9239	SHJO	*0701		-	-	-	-	-	-	-	-
46	9013	SCHU	*1501		-	-	-	-	-	-	-	-
47	9045	TUBO	*1104	*1201	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0103		-	-	-	-	-	-	-	-

Lot No.: **72E**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*08 SSP

Product number: 101.127-12u/04u – without *Taq* pol.
Lot number: 72E
Expiry date: 2010-June-01
Number of tests: 12 tests – Product No. 101.127-12u
4 tests – Product No. 101.127-04u
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2003-216-01	9	2003-216-09	17	2006-212-17
2	2003-216-02	10	2003-216-10	18	2006-212-18
3	2003-216-03	11	2003-216-11	19	2003-216-19
4	2004-171-04	12	2004-171-12	20	2003-216-20
5	2003-216-05	13	2008-476-13	21	2003-216-21
6	2003-216-06	14	2003-216-14	22	2008-476-22
7	2003-216-07	15	2003-216-15	23	2003-216-23
8	2003-216-08	16	2004-171-16	24	2004-171-24

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions No. 9, 11, 12, 13, 17 to 24 were available. The specificities of the primers in primer solutions 9, 11, 18, 20, 21 and 23 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solutions 12, 13, 19 and 22 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 17 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2009-May-26

Approved by:

Quality Control, Supervisor

Lot No.: **72E**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*08
Product number: 101.127-12u/04u
Lot number: 72E

Intended use: DRB1*08 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2000 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2009-May-26

Olle Olerup
Managing Director

Lot No.: **72E**

Lot-specific information

Lot No.: **72E**

Lot-specific information

Lot No.: **72E**

Lot-specific information

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